§ 807.37 Inspection of establishment registration and device listings.

(a) A copy of the forms FD–2891 and FD–2891a filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district office. Upon request, verification of registration number or location of a registered establishment will be provided.

(b)(1) The following information filed under the device listing requirements will be available for public disclosure:

(i) Each form FD–2892 submitted;

(ii) All labels submitted;

(iii) All labeling submitted;

(iv) All advertisements submitted;

(v) All data or information that has already become a matter of public knowledge.

(2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850.

(3) Requests for device listing information not identified in paragraph (b)(1) of this section shall be submitted and handled in accordance with Part 20 of this chapter.

[43 FR 37999, Aug. 25, 1978, as amended at 53 FR 11252, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 807.39 Misbranding by reference to establishment registration or to registration number.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

Subpart C—Registration Procedures for Foreign Device Establishments

§ 807.40 Establishment registration and device listing for U.S. agents of foreign manufacturers of devices.

(a) Each foreign device manufacturer who exports devices into the United States shall designate a person as their U.S.-designated agent, who is responsible for:

(1) Submitting MDR reports,

(2) Submitting annual certifications,

(3) Acting as the official correspondent,

(4) Submitting registration information,

(5) Submitting device listing information, and

(6) Submitting premarket notifications.

(b) The foreign manufacturer shall provide FDA with a statement of authorization for their U.S.-designate to perform MDR reporting duties under part 803 of this chapter, and to register, list, and submit premarket notifications under this part. The foreign manufacturer must provide this statement of authorization along with the name, address, and telephone number of the person initially designated, or any subsequent person designated as the U.S.-designated agent, within 5 days of the initial or subsequent designation. Information shall be sent to the Center for Devices and Radiological Health, Medical Device Reporting, Food and Drug Administration, P.O. Box 3002, Rockville, MD 20847–3002.

(c) The U.S.-designated agent of a foreign device manufacturer that exports devices into the United States is required to register the foreign manufacturer's establishments or places of business, and to list the foreign manufacturer's devices, in accordance with subpart B of this part, unless exempt under subpart D of this part, and to submit premarket notifications in accordance with subpart E of this part. The information submitted shall be in the English language.

[60 FR 63606, Dec. 11, 1995]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, § 807.40 was stayed indefinitely.

Subpart D—Exemptions

§ 807.65 Exemptions for device establishments.

The following classes of persons are exempt from registration in accordance with § 807.20 under the provisions of section 510(g) (1), (2), and (3) of the act, or because the Commissioner has found, under section 510(g)(4) of the act, that such registration is not necessary for the protection of the public health:

(a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of this part.

(b) A manufacturer of devices to be used solely for veterinary purposes.

(c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses.

(d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice.

(e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name, e.g., a properly labeled health aid such as an elastic bandage or crutch, indicating ''distributed by'' or ''manufactured for'' followed by the name of the pharmacy.

(f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution.

(g) [Reserved]

(h) Carriers by reason of their receipt, carriage, holding or delivery of devices in the usual course of business as carriers.

(i) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (i.e., patient, physician, layman, etc.) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic x-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.

(j) Distributors of cigarettes or smokeless tobacco as defined in part 897 of this chapter.

[42 FR 42526, Aug. 23, 1977, as amended at 58 FR 46523, Sept. 1, 1993; 61 FR 44615, Aug. 28, 1996]

EFFECTIVE DATE NOTE: At 61 FR 44615, Aug. 28, 1996, § 807.65 was amended by adding paragraph (j), effective Aug. 28, 1997.

Subpart E—Premarket Notification Procedures

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to, (i) a device in commercial distribution before May 28, 1976, or (ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in